REMARKS

Claims 1-3, 8 and 10 are pending in the present application. Claims 1 and 10 have been amended. Claims 4-7 and 9 have been cancelled without prejudice or disclaimer.

Applicants, by amending or cancelling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claim 1 has been amended to recite a "patch comprising a backing layer and an adhesive layer disposed on the backing layer, the adhesive layer consisting of oxybutin and/or a pharmaceutically acceptable salt thereof; a pharmaceutically acceptable excipient selected from the group consisting of an organic acid, a skin permeation enhancer, an absorption enhancer, a plasticizer, a tackifier, an antioxidant, a filler and an ultraviolet absorber; 1-5% by weight of a 2-ethylhexyl acrylate-vinyl acetate copolymer based on the total weight of the adhesive agent, the 2-ethylhexyl acrylate-vinyl acetate copolymer being substantially free of both carboxyl groups and hydroxyl groups in the molecule; and 10-25% by weight of a styrene-isoprene-styrene block copolymer based on the total weight of the adhesive agent, wherein the weight ratio of the 2-ethylhexyl acrylate-vinyl acetate copolymer to the styrene-isoprene-styrene block copolymer is from 1:4 to 1:19." Support for the amendment to claim 1 can be found throughout the specification and claims as originally filed.

Claim 10 has been amended to depend from claim 1. Support for the amendment to claim 10 can be found throughout the specification and claims as

originally filed.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. Interview

Applicants respectfully thank Examiner Mercier and her Supervisor for conducting an interview with Applicants' undersigned representative on August 12, 2010. During the interview, Applicants proposed amending the claims as reflected in the above listing of claims. The Examiners agreed that the proposed amendment to the claims overcomes all of the rejections of record.

In addition, the Examiners requested that Applicant verify that the present application and US Patent No. 7,615,237 (the '237 patent) were commonly owned at the time the claimed subject matter was invented. Applicants respectfully hereby submit that US Patent No. 7,615,237 and the present application were each assigned to, and therefore owned by, the same entity, i.e., Hisamitsu Pharmaceutical Co., Inc. (408, TASHIRODAIKAN-MACHI, TOSU-SHI, SAGA 841-0017, Japan) at the time of invention of the presently claimed subject matter. Further, since the '237 patent would only be considered prior art against the present application under 35 USC § 102(e), a rejection of the present claims in view of the '237 patent would not be proper for at least the reason that the subject matter claimed was, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. *See* 35 USC § 103(c).

In view of the foregoing, Applicants respectfully submit that the present application is in condition for allowance.

II. At page 3 of the Official Action, claims 1, 3 and 8-9 have been provisionally rejected under the doctrine of non-statutory double patenting over claims 1, 3, 6, 8, 9-11 and 13-14 of co-pending US Patent Application No. 10/469,612 (Tateishi et al.).

The Examiner asserts that the claims are not patentably distinct from claims 1, 3, 6, 8, 9-11 and 13-14 of co-pending U.S. Patent Application No. 10/469,612.

Applicants respectfully submit that this rejection has been obviated in view of the amendments herein. Accordingly, Applicants request that the Examiner reconsider and withdraw this rejection.

III. At page 3 of the Official Action, claims 1-3 and 8-10 have been rejected under 35 USC § 103(a) as being unpatentable over Houze et al. (US Patent Application No. 2002/0058068) in view of Sablotsky (US Patent No. 4,994,267) and in further view Gale (US Patent No. 5,614,211).

The Examiner asserts that it would have been obvious to use the styrene-isoprene-styrene block co-polymers of Sablotsky in the composition of Houze et al. and to incorporate oxybutin as an active ingredient, as evidenced by Gale.

In view of the foregoing, Applicants respectfully traverse the rejection of claims 1-3, 8 and 10. Applicants submit that the rejection of claim 9 has been rendered moot by the cancellation of the same.

To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U. S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established

functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. at 417). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Regarding motivation to modify properly combined references, **MPEP 2143** states that where the prior art conflicts, all teachings must be considered and that the fact that references can be combined or modified is not sufficient to establish *prima facie* obviousness. **MPEP 2143** further states that there must be some suggestion or motivation to modify the references, and there must be a reasonable expectation of success. In addition, the prior art reference or references when properly combined, must teach or suggest all the claim limitations.

MPEP 2143.01 states that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. If it does, then there is no suggestion or motivation to make the proposed modification. Further, the proposed modification cannot change the principle operation of a reference.

It is submitted that a proper case of *prima facie* obviousness has not been established because, whether taken alone or in combination, none of the cited references teach or suggest each and every element of the presently pending claims as required by *In re Wilson*. Further, Applicants submit that there is no motivation to modify Houze et al. to achieve the presently claimed subject matter because doing so would render the dermal compositions described therein unsatisfactory for its intended purpose.

Independent claim 1 is directed to a patch comprising a backing layer and an adhesive layer disposed on the backing layer, the adhesive layer consisting of oxybutin and/or a pharmaceutically acceptable salt thereof; a pharmaceutically acceptable excipient selected from the group consisting of an organic acid, a skin permeation enhancer, an absorption enhancer, a plasticizer, a tackifier, an antioxidant, a filler and an ultraviolet absorber; 1-5% by weight of a 2-ethylhexyl acrylate-vinyl acetate copolymer based on the total weight of the adhesive agent, the 2-ethylhexyl acrylate-vinyl acetate copolymer being substantially free of both carboxyl groups and hydroxyl groups in the molecule; and 10-25% by weight of a styrene-isoprene-styrene block copolymer based on the total weight of the adhesive agent, wherein the weight ratio of the 2-ethylhexyl acrylate-vinyl acetate copolymer to the styrene-isoprene-styrene block copolymer is from 1:4 to 1:19. Claims 2-3 and 8-10 depend, either directly or indirectly,

from claim 1.

In contrast, Houze et al. is directed to a dermal composition for administration of a drug comprising a blend of two or more acrylic-based polymers having differing functionalities. *See* Houze et al. at the abstract.

Sablotsky is directed to a dermal composition comprising a drug, a multipolymer of ethylene-vinyl acetate, an acrylic polymer, and optionally one or more monomers, a natural or synthetic rubber and a tackifying agent. *See* Sablotsky at the abstract.

Gale is directed to a device for the transdermal administration of oxybutynin comprising a microporous tie layer located between the oxybutynin reservoir and the contact adhesive. *See* Gale at the abstract.

However, unlike the presently claimed subject matter, whether taken alone or in combination, none of the cited references teach or suggest ***an adhesive layer consisting of oxybutin and/or a pharmaceutically acceptable salt thereof***; ***a pharmaceutically acceptable excipient*** selected from the group consisting of an organic acid, a skin permeation enhancer, an absorption enhancer, a plasticizer, a tackifier, an antioxidant, a filler and an ultraviolet absorber; ***1-5% by weight of a 2-ethylhexyl acrylate-vinyl acetate copolymer*** based on the total weight of the adhesive agent, the 2-ethylhexyl acrylate-vinyl acetate copolymer being substantially free of both carboxyl groups and hydroxyl groups in the molecule; and ***10-25% by weight of a styrene-isoprene-styrene block copolymer*** based on the total weight of the adhesive agent, wherein the weight ratio of the 2-ethylhexyl acrylate-vinyl acetate copolymer to the styrene-isoprene-styrene block copolymer is from 1:4 to 1:19, as recited in claim 1. Accordingly, the cited references do not teach or suggest each and

every element of the presently claimed subject matter.

In addition, Applicants submit that there is no motivation to modify Houze et al. to achieve the presently claimed subject matter because doing so would render the dermal compositions described therein unsatisfactory for its intended purpose. In this regard, Applicants note that Houze et al. describe the use of two different functional acrylic-based polymers in the compositions disclosed therein to achieve good adhesion properties, controllable drug solubility and flux. See paragraph [0037] of Houze et al. However, Houze et al. describe the use of Duro-Tak 87-2097 as a non-functional acrylic-based polymer that must combined with the two essential acrylic-based polymers having different functionalities. Accordingly, Applicants submit that ***without using the two different functional acrylic-based polymers, the composition of Houze et al. cannot achieve its intended purpose***. Since the present claims exclude such a formulation, there is no motivation to modify Houze et al. to achieve the presently claimed subject matter.

In view of the foregoing, Applicants submit that nothing in any of the cited references, whether taken alone or in combination, renders the subject matter of present claims 1-3, 8 and 10 obvious, within the meaning of 35 USC § 103. Thus, the Examiner is respectfully requested to reconsider and withdraw this rejection of claims 1-3, 8 and 10.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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